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10/510,132

10/04/2004

Tsutomu Furuzono

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EXAMINER

MILLER, DANIEL H

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

09/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/510,132 | Applicant(s) FURUZONO ET AL. | |
| | Examiner DANIEL MILLER | Art Unit 1794 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/10/2008 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes (US 6,968,234) in view of Gagliardi (US 3,547,688).

3. Stokes teaches a medical device having a casing formed from a polymer material that can be a silicone rubber (abstract). The polymer casing has active groups attached to the base polymer that covalently bond to biologically active agents (abstract).

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4. However, Stokes is silent as to amido groups complexed with titanium oxide.

5. Gagliardi (US 3,547,688) teaches it has been known in the art for 40 years to incorporate complex salts of silver with amido groups into plastic (see abstract) medical devices for antibacterial effects (column 2 line 30-35).

6. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate silver amido salts (which would be expected to complex with titanium oxide and function as claimed) into the composition of Stokes in order to obtain antimicrobial benefits in the medical device.

7. The material inherently has photocatalyst properties due to its composition and the optical characteristics of titanium oxide.

8. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes (US 6,968,234) in view of Lomas (US 6,716,908) and further in view of Furuya et al (US 6,048,910).

9. Stokes teaches a medical device having a casing formed from a polymer material that can be a silicone rubber (abstract). The polymer casing has active groups attached to the base polymer that covalently bond to biologically active agents (abstract).

10. However, while Stokes teaches covalent bonding it does not specifically teach hydroxyl groups or an alkoxysilyl functional group as claimed.

11. Lomas teaches that it is well known in the art to provide alkoxysilyl functionalized silicone polymers in personal care products and that such functionalized silicone polymer materials usually have the advantage of providing superior durability, enhanced

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thermodynamically stability, and have good aesthetic (column 1 lines 45-55, 65- column 2 lines 1-4 Lomas).

12. However, Lomas does not teach hydroxyl functional groups.

13. Furuya et al (US 6,048,910) teaches a coating can be rendered hydrophilic by adding particulate photocatalysts, typically titanium oxide. When the photocatalyzed coating is irradiated with UV-containing light, the coating acquires a hydrophilicity such that the water-drop contact angle of the coating surface becomes 10.degree. or less (column 1 lines 42-50). This is regarded as a hydrophilization system in which electrons and holes form at the surface of the photocatalyst particles upon exposure to light; and oxygen and water in the air are oxidized and reduced here, generating active radical species which then partially decompose the silicone resin they are attached to serving as the binder, forming hydrophilic silanol groups at the surface, where moisture in the air is then adsorbed (column 1 lines 42-65). Deposited organic contaminants are self-cleaned from the coating surface with water. Even the contaminants that firmly adhere to the coating surface are completely oxidized and decomposed by the radical species generated in situ, and hydrophilic properties are thus maintained (column 1 lines 42-65). Furthermore, because numerous hydroxyl groups are present at the surface of photocatalyst particles, typically titanium oxide the particles are strongly bound to the binder resin (silicone) and are not carried away from the coating (column 1 lines 42-65). The binder resin is not carried away and the properties can be sustained semi-permanently (column 1 lines 65-68).

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14. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a silicone polymer comprising have alkoxysilyl functional groups because they have the advantage of providing superior durability, enhanced thermodynamically stability, and have good aesthetic and it would further be obvious to provide hydroxyl complexed titanium oxide complexes because the titanium oxide is inherently an antibacterial agent and functions to self-clean organic contaminants from the coating surface with water which is useful when employed as a medical device coating as in Stokes.

15. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes (US 6,968,234) in view of Lomas (US 6,716,908) and further in view of Furuya et al (US 6,048,910) as applied to claim 6 above, and still further in view of JP402109570A.

16. Stokes (US 6,968,234) in view of Lomas (US 6,716,908) and further in view of Furuya et al do not teach the use of silkfibroin as a polymer material.

17. JP402109570A teaches that silkfibroin is a material that can be employed for various medical materials (translation abstract).

18. It is prima facie obvious to substitute known materials for the same purpose.

19. Therefore, It would have been obvious to one of ordinary skill in the art at the time of the invention to use silkfibroin in the composition of JP2002331028 because it is taught to be a good choice of materials for medical devices.

20. Claims 1, and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP2002331028 in view of Gagliardi (US 3,547,688).

21. JP2002331028 teaches a tubular medical device made from an elastomer (polymer) having a photocatalyst layer comprising titanium oxide (Derwent abstract). The surface is treated with acid (functionalized) and then is considered to be bonded directly to the titanium oxide (see translation abstract).

22. However, the JP reference is silent as to the presence of amido groups.

23. Gagliardi (US 3,547,688) teaches it has been known in the art for 40 years to incorporate complex salts of silver with amido groups into plastic (see abstract) medical devices for antibacterial effects (column 2 line 30-35).

24. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate silver amido salts (which would be expected to complex with titanium oxide and function as claimed) into the composition of JP in order to obtain antimicrobial benefits in the medical device.

25. The material inherently has photocatalyst properties due to its composition and the optical characteristics of titanium oxide.

Response to Arguments

26. Applicant's arguments filed 9/10/2008 have been fully considered but they are not persuasive.

27. Applicant argues that,

28. *"Stokes states: 'The use of silver ion has been promoted as bactericidal. Silver received a bad name because it apparently also inhibits the healing process, resulting in blood leakage around treated valve sewing rings, for example' (see col. 1, lines 47 to 50). Accordingly, the invention of Stokes is focused mainly on using the biologically active agents instead of chemical substances such as silver in order to prevent or reduce infections centered at an implanted medical device. Therefore, the application of the complex salts of silver with amido groups of Gagliardi to the Stokes device is not warranted, because it is against the spirit and teachings of the invention of Stokes."*

29. Even if applicant's argument is accepted, it can not be reasonably concluded that just because the "focus" of the reference is to a particular aspect of a technology, that this would amount to a teaching away from the combination. When combining the references in a 103 the examiner must look to both the teachings of the references and what one of ordinary skill in the art would have known at the time of the invention. Clearly based on the teachings of the Gagliardi It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate silver amido salts (which would be expected to complex with titanium oxide of JP or Furuya et al (US 6,048,910) and function as claimed) into the composition of JP or Stokes in order to obtain antimicrobial benefits in the medical device.

30. No patentable distinction is seen. Rejection maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL MILLER whose telephone number is (571)272-1534. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571)272-14011. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Daniel Miller

/KEITH D. HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794